REMARKS

Claims 1-4, 6-7, 9-10, 13-20, have been cancelled. Claims 5, 8, 11, 12, 21, 22, and 25 have been amended. New claims 29-30 are added. Claims 5, 8, 11-12, and 21-30 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

The Examiner's indication in the last Office Action that claims 1, 3-5, 8, 11-12, and 21 are deemed free of the prior art is gratefully acknowledged.

Support for claim amendments

Support for the amendment of DNA (b) in claims 5 and 11 is found in cancelled claim 3 and on page 21, line 11 to page 26, line 7; and page 23, line 24 to page 25, line 4 of the present specification.

Support for the amendment of DNA (d) in claim 11 is found in cancelled claims 6 and 7 and on page 24, lines 6-12 and page 25, lines 8-14 of the specification.

Support for the new claims 22 and 23 is found in cancelled claim 4 and on page 24, line 21 to page 25, line 2 of the specification.

Claim objections

Claims 22 and 25 and claims 23-24 and 26-28 dependent thereon are objected to under 37 C.F.R. § 1.75(c) as being multiply dependent and depending from another multiple dependent claim.

Claim 8 is no longer multiply dependent. Accordingly, none of the claims (8, 11, 12, and 21) from which claims 22 and 25 depend are now multiply dependent and it is respectfully submitted that claims 22 and 25 are now properly multiply dependent.

Withdrawal of the objection to claims 22-28 is requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3-5, 8, and 11 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) has possession of the claimed invention at the time that the application was filed.

The Office Action states that the specification does not describe MITE-like elements that are capable of causing duplication of a genus of target sequences (A)nG(A)n (n being an integer not less than 1) at the insertion site thereof in a genomic gene. The Examiner takes the position that the disclosure of SEQ ID NO: 1 is not sufficient to enable other sequences within the genus. Furthermore, the Office Action continues that the specification does not describe MITE-like elements that are capable of causing duplication of a genus of target sequences (A)nG(A)n (n being an integer not less than 1) at the insertion site thereof in a genomic gene and that have a genus of perfect terminal inverted repeat sequences in their 5' and 3' terminal regions or that have a genus of imperfect terminal inverted repeat sequences in their 5' and 3' terminal regions. The Office Action asserts that the specification does not describe a genus of MITE-like elements that are capable of causing duplication of the target sequence (A)nG(A)n (n being an integer not less than 1) at the insertion site thereof in a genomic gene and that comprise a genus of DNAs capable of hybridizing with a DNA having a complementary sequence to SEQ ID NO: 1 under stringent conditions. The Office Action asserts that the specification does not describe or characterize any element or construct containing at least one MITE-like element that has transcriptional activation activity. The specification also does not describe or characterize any transcriptional activation element containing at least one MITE-like element that functions as a transposable element. The specification does not describe a genus of recombinant DNA constructs comprising a tandem coupling product from a MITE-like element.

In response to the above ground of rejection, Applicants have amended claim 5 and cancelled claims 1, 3, and 4. In claim 5, the term "comprising" has been replaced with the closed language "consisting of." Part (a) recites "a DNA having a nucleotide sequences shown under SEQ ID NO: 1" which the Examiner has indicated as enabled. Part (b) has been amended to recite-

a DNA, capable of causing duplication of the target sequence: (A)nG(A)n [n being an integer of not less than 1] at the site of insertion thereof in a genomic gene, which contains a plurality of repeat sequences represented by formula (1): XttgcaaY (wherein X represents g or t and Y represents a or c) in the terminal inverted repeat sequences thereof, and in the intermediate region between the terminal inverted repeat sequences, a plurality of repeat sequences represented by formula (1) and formula (2): Zatgcaa (wherein Z represents t or a), and which has a nucleotide sequence not less than 85% homologous with the nucleotide sequence shown under SEQ ID NO: 1.

Claims 8, 11, and 22-30 depend ultimately from claim 5. Claim 5 as amended is believed to meet the written description requirement of 35 U.S.C. § 112, first paragraph for the following reasons.

The Examiner takes the position that the disclosure of SEQ ID NO: 1 is not sufficient to enable other sequences within the genus. However, the DNA of part (b), as amended, is a functional equivalent of the DNA of part (a) (SEQ ID NO: 1) and has a nucleotide which is at least 85% homologous with the nucleotide sequence of part (a) (SEQ ID NO: 1). The Examiner has indicated that claims directed to SEQ ID NO: 1 meet the requirements of 35 U.S.C. § 112, first paragraph. Applicants respond that the skilled artisan would be able to isolate other genus members based upon the disclosed sequence corresponding to SEQ ID NO:1. In support of this position, Applicants submit Attachment 1 (Bureau, et al. (October 1992) The Plant Cell 4: 1283-1294) and Attachment 2 (Bureau, et al. (June 1994) The Plant Cell 6: 907-916 (attached). These references disclose that MITEs belonging to the same family have common nucleotide sequences in both terminal regions thereof. Attachment 3 (Casacuberta, et al. (1998) The Plant Journal 16(1):79) discloses a novel MITE, Emigrant, and cloning of 14 MITEs belonging to the same family by in silico screening utilizing the characteristic of MITEs that the sequence in both terminal regions is highly conserved. Accordingly one skilled in the art at or before the time of the claimed invention could reasonably expect to be able to isolate functional equivalents of MITE-like elements such as SEQ ID NO: 1 that had 85% sequence homology to SEQ ID NO: 1 by hybridization, using the well known conservation of the 5' and 3' ends.

Attachments 4 (Biedler, et al. (2003) Insect Molecular Biology 12 (3) :211) and 5 (Casa, et al. (2004) Methods Mol Biol. 260: 175 (Abstract)) are directed to transposon display procedures which exploit the characteristic of MITEs discussed above, that is, that the terminal regions are highly conserved. The disclosed process includes synthesizing a DNA primer(10-20 bp) which binds to a sequence in the terminal region of a MITE and amplifying a full-length MITE in genomic DNA by PCR using the synthesized primer. The technique is based upon the well known characteristic that MITEs belonging to the same family have common nucleotide sequences in both terminal regions. This means that MITEs belonging to the same family have common nucleotide sequences in both terminal regions to the extent that the sequence homology is at least 80% to allow hybridization.

Accordingly, the claims as amended are believed to meet the written description requirement of 35 U.S.C. § 112, first paragraph. It was well known in the art that MITE sequences could be used to isolate other members of the genus having the recited property of "capable of causing duplication of the target sequence: (A)nG(A)n [n being an integer of not less than 1] at the site of insertion thereof in a genomic gene, which contains a plurality of repeat sequences represented by formula (1): XttgcaaY (wherein X represents g or t and Y represents a or c) in the terminal inverted repeat sequences thereof, and in the intermediate region between the terminal inverted repeat sequences, a plurality of repeat sequences represented by formula (1) and formula (2): Zatgcaa (wherein Z represents t or a)" utilizing the property that the 5' and 3' ends are highly conserved.

The Office Action also states that the specification does not describe MITE-like elements that are capable of causing duplication of a genus of target sequences (A)nG(A)n (n being an integer not less than 1) at the insertion site thereof in a genomic gene and that have a genus of perfect terminal inverted repeat sequences in their 5' and 3' terminal regions or that have a genus of imperfect terminal inverted repeat sequences in their 5' and 3' terminal regions. This ground of rejection is believed to be overcome by Applicants' claim amendments as the claims no longer recite "perfect" or "imperfect" terminal repeat sequences.

The Office Action asserts that the specification does not describe a genus of MITE-like elements that are capable of causing duplication of the target sequence (A)nG(A)n (n being an integer not less than 1) at the insertion site thereof in a genomic gene. However, the characteristic that the isolated MITE is "capable of causing duplication of the target sequence: (A)nG(A)n" is merely a characteristic of the claimed DNA. It is not necessary to explain the mechanism behind transposition of MITE-like sequences in order to isolate other MITE-like sequences and in order to use the invention as claimed. As explained above, other MITE-like sequences may be isolated by utilizing the well-known conservation of sequence at the 5' and 3' ends. The MITE-like sequences have a disclosed use as transcription activation elements. As shown in Figures 12 and 13, inclusion of the IS1 and/or IS2 element when transforming tobacco cells leads to more viable cells due to an increase in expression of kanamycin resistance in the cells which include the IS1 and/or IS2 element. Similar results were obtained using regenerated tobacco plants (Table 2), carrot somatic embryos (Table 3), and rice (Table 4). Applicants

respectfully submit that the claimed invention is sufficiently described such that one skilled in the art could practice the claimed invention.

The Office Action also states that the specification does not teach a DNA having a complementary sequence to SEQ ID NO: 1 under stringent conditions. This ground of rejection is believed to be overcome by amendment of claim 5 to recite "not less than 85% homologous with the nucleotide sequences shown under SEQ ID NO: 1." Support for this amendment is found in the present specification at page 24, line 1, for example.

The Office Action asserts that the specification does not describe or characterize any element or construct containing at least one MITE-like element that has transcriptional activation activity. As set forth by the Examiner herself in the Office Action, the specification describes 3 different MITE/promoter fusion constructs. The activity of these constructs is described in Figures 12 and 13. As shown in Figures 12 and 13, inclusion of the IS1 and/or IS2 element when transforming tobacco cells leads to more viable cells due to an increase in expression of kanamycin resistance in the cells which include the IS1 and/or IS2 element. Similar results were obtained using regenerated tobacco plants (Table 2), carrot somatic embryos (Table 3), and rice (Table 4). Consequently, Applicants believe that there is sufficient written description for "transcriptional activation activity" in the present specification based upon the characterization of these three different constructs.

The Office Action also asserts that the specification does not describe or characterize any transcriptional activation element containing at least one MITE-like element that functions as a transposable element. Applicants submit that one skilled in the art would identify the described MITE-like elements as transposable elements based upon their characteristics as claimed and as described in the present specification.

The Office Action states that the specification does not describe a genus of recombinant DNA constructs comprising a tandem coupling product from a MITE-like element. In response, such a tandem coupling product is described, for example, at page 30, lines 12-23 and also exemplified at page 48, line19 to page 49, line 6 and also Figure 9. Applicants submit that the above-referenced sections provide sufficient written description for the claimed embodiment.

Isolation of MITE-like elements that are functionally equivalent to SEQ ID NO: 1 is clearly well within the skill in the art. Applicants were the first to discover this particular family of MITE-like elements. Limitation of the claims to this single embodiment would unfairly allow

others to easily practice Applicants' invention without infringing Applicants claim by using the methodology as discussed above and as disclosed in the five (5) attached references to isolate other MITE-like elements within the genus. As Applicants were the first to discover this family of MITE-like elements, Applicants believe that they are entitled at least to the claim breadth as recited in claim 5 as amended.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 1, 3-5, 8, 11-12, and 21 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated miniature inverted-repeat transposable element (MITE)-like element having the nucleotide sequence of SEQ ID NO: 1, a recombinant DNA element having the nucleotide sequence of SEQ ID NO: 3, and a recombinant DNA element having the nucleotide sequence of SEQ ID NO: 14, does not reasonably provide enablement for other isolated MITE-like elements, or isolated MITE-like element that are capable of causing duplication of a target sequence, or other recombinant DNA elements or recombinant DNA elements that activate transcription or that transpose.

This rejection is similar to the rejection above and Applicants' comments above are incorporated herein by reference.

The Examiner posits that it would require undue experimentation to obtain genus members other than SEQ ID NO: 1 and that it is not predictable that other MITE-like elements that structurally and functionally resemble the IS2 mite of SEQ ID NO: 1 could be found in other plant species. However, Applicants argue that isolation of related MITE-like elements was well known at the time of the invention. This position is supported by the 5 references which are provided. The discussion of these five references above is incorporated here by reference.

In addition, Applicants have limited the claims to either SEQ ID NO: 1 (which the Examiner admits is enabled) or to "a DNA capable of causing duplication of the target sequence: (A)nG(A)n [n being an integer of not less than 1] at the site of insertion thereof in a genomic gene, which contains a plurality of repeat sequences represented by formula (1): XttgcaaY (wherein X represents g or t and Y represents a or c) in the terminal inverted repeat sequences thereof, and in the intermediate region between the terminal inverted repeat sequences, a plurality of repeat sequences represented by formula (1) and formula (2): Zatgcaa (wherein Z represents t

or a)" which is also 85% homologous to SEQ ID NO: 1. The scope of the claim is clearly defined and it was within the skill in the art to isolate such sequences. Furthermore, one skilled in the art would expect to find other sequences falling within the scope of the present claims, as indicated by the attached references. Consequently, Applicants submit that the present claims are of appropriate scope and are enabled by the present specification.

The Examiner also asserts that the specification does not provide sufficient guidance with respect to how to use the disclosed MITE-like sequences to duplicate a target sequence or transpose. However, the characteristic that the isolated MITE is "capable of causing duplication of the target sequence: (A)nG(A)n" is merely a characteristic of the claimed DNA. That is, other MITE-like sequences falling within the genus also have a target duplication sequence as claimed. It is not necessary to explain the mechanism behind transposition of MITE-like sequences in order to isolate other MITE-like sequences and in order to use the invention as claimed. As explained above, other MITE-like sequences may be isolated by utilizing the well-known conservation of sequence at the 5' and 3' ends. The MITE-like sequences have a disclosed use in the specification as transcription activation elements. As shown in Figures 12 and 13, inclusion of the IS1 and/or IS2 element when transforming tobacco cells leads to more viable cells due to an increase in expression of kanamycin resistance in the cells which include the IS1 and/or IS2 element. Similar results were obtained using regenerated tobacco plants (Table 2), carrot somatic embryos (Table 3), and rice (Table 4).

The Examiner also questions whether the specification teaches how to activate transcription. In response, Applicants have shown increased growth due to increased expression of kanamycin resistance in three different species: tobacco, carrot and rice; in whole plants (tobacco) and undifferentiated cells (tobacco and rice) and somatic embryos (carrot); in dicots (tobacco and carrot) and monocots (rice). Results were consistent for these diverse species and tissue types. While the Examiner states that other mechanisms could be proposed to account for the increased transformation efficiency and regeneration efficiency, it is not necessary for Applicants to understand the mechanism by which their invention works. The results are clear and consistent that MITE-like elements according to the invention produce an increase in growth. Consequently, one skilled in the art would recognize that the claimed elements could be used to activate transcription.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 101

Claims 1, 3-5, 8, 11-12, and 21 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

This ground of rejection is believed to be overcome by amendment of the claims to recite that the claimed invention is directed to "isolated" miniature inverted-repeat transposable elements. Consequently, the claims are now directed to statutory subject matter.

Withdrawal of the above ground of rejection is respectfully requested.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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